Remarks

Claims 20-38 were pending for purposes of the instant Office Action, which has been made final. Claims 20 and 27 have been amended, as shown above. The subject matter of Claims 23, 25, 30, and 32 has been incorporated into the independent Claims 20 and 27. Accordingly, Claims 23, 25, 30 and 32 have been canceled. Claims 34-38 have also been canceled. Therefore, claims 20-22, 24, 26-29, 31 and 33, as amended, remain pending. No new mater is added by the amendments to the claims as currently presented. A Listing of Claims is provided at page 6, below. Reconsideration and allowance of the currently pending claims is respectfully requested.

Applicants first thank the Examiner for carefully considering the previous Reply and amendments, and gratefully acknowledge the withdrawal of the rejections based on the references of Pence, et al., Hsu, et al., previously cited separately and combined with various references. Certain other rejections, however, remain, and are addressed herein below

Claims 20-38 have been rejected under 35 USC 112, second paragraph, as providing insufficient antecedent basis for "said 25-dihydroxyvitamin D or its analog, salt, or derivative thereof." Applicants believe this recitation to be an inadvertent typographical error. The proper recitation should be "25-hydroxyvitamin D." A correction has been made to the claims by the above amendment, in accordance with the proper recitation. Applicants respectfully submit that proper antecedent basis is provided for the recitation of "25-hydroxyvitamin D", and requests the rejection under 35 USC 112, second paragraph be withdrawn.

Claims 34-38 were rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement. Although applicants respectfully disagree, and reserve the right to pursue such subject matter in a continuing application, it is noted that Claims 34-38 have been cancelled in the instant application. Accordingly, this rejection is now moot. Withdrawal of the rejection under 35 USC 112, first paragraph, is respectfully requested.

Claims 20, 22-23, 25-27, 29-30 and 32-33 have been rejected under 35 USC 102(b) as being anticipated by Raina, et al. (Br. J. Cancer 1991: 463-465) (hereinafter "Raina"). However, the rejection relies on the disclosure of Raina as teaching a method of treating progressive low-grade non-Hodgkin's lymphoma. Applicant respectfully directs the Examiner's attention to the amended claims, in which the recitation of treating lymphoma (and other non-solid tumors, such as leukemia) has been deleted. Although applicant disagrees that Raina anticipates the subject invention, including for the reasons of record, it is clear that lymphomas are not part of the instant claims, as amended. Accordingly, Raina does not anticipate the current claims and reconsideration and withdrawal of the rejection under 35 US 102(b) is respectfully requested.

Next, Claims 20, 22-27, and 29-33 stand rejected under 35 USC 102(b) as being anticipated by Getzenberg, et al. (Urology 1997; 50: 999-1006) (hereinafter "Getzenberg"). In contrast to the claimed invention, Getzenberg describes only administering 1,25-D3 and the analogue, Ro25-6760. The analogue Ro25-6760 is identified in Getzenberg as 1,25-dihydroxy-16-ene-23-yne-26,27-hexafluoro-19-nor-chloecalciferol; thus, Ro25-6760 is dihydroxylated, including

It would be readily understood by persons of ordinary skill in this art that the 100-500 mcg/day doses of 25-hydroxyvitamin D described by Haussler would result in intracellular levels in tissues other than bone, well above (likely to be orders of magnitude greater than) the concentration of between 25 and 250 nmol/L as expressly claimed. In the presence of the 1-alpha-hydroxylase enzyme in tissues other than bone, the doses described by Haussler can produce levels of 1,25-dihydrxyvitamin D well above 350 nmol/L which, as stated in the subject application, is considered "dangerous" to the health of the individual. This dangerous intracellular concentration is exactly what is avoided by the subject method, where intracellular concentrations of the administered composition are limited to the claimed normal levels.

By describing a treatment for bone disorders using very high doses of 25-hydroxyvitamin D, Haussler does not provide a teaching that would lead a person of ordinary skill in the art to substitute 25-hydroxyvitamin D for the 1,25-dihydroxyvitamin D taught by Getzenberg. The combination of references does not teach or suggest that 25-hydroxyvitamin D can be used to prevent or treat certain cancers, such as prostate cancer – especially using the low effective doses providing intracellular levels of 1,25-dihydroxyvitamin D (the metabolite) within the normal range of 25-250 nmol/L, as claimed. Accordingly, the references of Getzenberg in view of Haussler would not have made obvious the subject method. It is respectfully requested that the rejection under 35 USC 103(a) be reconsidered and withdrawn.

Applicant believes the claims as currently presented in this Amendment are in condition for allowance and respectfully requests such action.

Applicant invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application.

Respectfully submitted,

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